K002165

Date: July 28. 2000

510(k) SUMMARY

SUBMITTED BY:

Bradford M. Spring
Manager, Regulatory Affairs
Becton Dickinson and Company
7 Loveton Circle
Sparks, MD 21152-0999
Phone: 410-316-4206
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NAME OF DEVICE:

Trade Name:	Linezolid 30 µg, BBL™ Sensi-Disc™
Common Name/Description:	Antimicrobial Susceptibility Test Discs
Classification Name:	Susceptibility Test Discs, Antimicrobial
PREDICATE DEVICE:	Other BBL™ Sensi-Disc™ such as Ciprofloxacin 5 µg, BBL™ Sensi-Disc™

DEVICE DESCRIPTION:

INTENDED USE:

Antimicrobial Susceptibility Test Discs are used for semi-quantitative *in vitro* susceptibility testing by standardized agar diffusion test procedures. Linezolid 30 µg BBL™ Sensi-Disc™ is intended for use in determining the susceptibility to Linezolid of a wide range of bacteria, as described under Indications for Use below. Zone sizes used for interpretation of tests, including control organism limits, were determined by the antimicrobic manufacturer, Pharmacia & Upjohn, and received FDA approval under NDA Nos. 21-130, 21-131 and 21-132.

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INDICATIONS FOR USE:

Use of Linezolid 30 µg, BBL™ Sensi-Disc™ for *in vitro* agar diffusion susceptibility testing is indicated when there is a need to determine the susceptibility of bacteria to Linezolid. Linezolid has been shown to be active *in vitro* against most strains of microorganisms listed below, as described in the Pharmacia & Upjohn package insert for this antimicrobic.

Active *In Vitro* and in clinical infections against:

Aerobic and facultative Gram-positive microorganisms
Enterococcus faecium (vancomycin-resistant strains only)
Staphylococcus aureus (including methicillin-resistant strains)
Streptococcus agalactiae
Streptococcus pneumoniae (penicillin-susceptible strains only)
Streptococcus pyogenes

Active *In Vitro* Against:

Aerobic and facultative Gram-positive microorganisms
Enterococcus faecalis (including vancomycin-resistant strains)
Enterococcus faecium (vancomycin-susceptible strains)
Staphylococcus epidermidis (including methicillin-resistant strains)
Staphylococcus haemolyticus
Streptococcus pneumoniae (penicillin-resistant strains)
Viridans group streptococci

PRODUCT DESCRIPTION:

Linezolid 30 µg BBL™ Sensi-Disc™ is prepared by impregnating high quality paper with accurately determined amounts of Linezolid supplied by the manufacturer, Pharmacia & Upjohn. Each Linezolid disc is clearly marked on both sides with the agent and content. Linezolid discs are furnished in cartridges of 50 discs each. Linezolid cartridges are packed as either a single cartridge in a single box, or in a package containing ten cartridges.

Agar diffusion methods employing dried filter paper discs impregnated with specific concentrations of antimicrobial agents were developed in the 1940's. In order to eliminate or minimize variability in the testing, Bauer et al. developed a standardized procedure in which Mueller Hinton Agar was selected as the test medium.

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PRODUCT DESCRIPTION (continued)

Various regulatory agencies and standards-writing organizations subsequently published standardized reference procedures based on the Bauer-Kirby method. Among the earliest and most widely accepted of these standardized procedures were those published by the U.S. Food and Drug Administration (FDA) and the World Health Organization (WHO). The procedure was adopted as a consensus standard by the National Committee for Clinical Laboratory Standards (NCCLS) and is periodically updated. The latest NCCLS documents are M2-A7 (1/00) and M100-S10 (1/00).

Discs containing a wide variety of antimicrobial agents are applied to the surface of Mueller Hinton Agar plates [or Haemophilus Test Medium Agar for *Haemophilus influenzae* or Mueller Hinton Agar with 5% Sheep Blood for *Streptococcus* species] inoculated with pure cultures of clinical isolates. Following incubation, the plates are examined and the zones of inhibition surrounding the discs are measured and compared with established zone size ranges for individual antimicrobial agents in order to determine the agent(s) most suitable for use in antimicrobial therapy. The determination as to whether the organism in question is susceptible (S), intermediate (I), or resistant (R) to an antimicrobial agent is made by comparing zone sizes to those found in the respective organism tables of NCCLS Document M2-A7 ("Performance Standards for Antimicrobial Disk Susceptibility Tests - Seventh Edition, Approved Standard", 1/00) and of NCCLS Document M100-S10 ("Performance Standards for Antimicrobial Susceptibility Testing", Tenth Informational Supplement, 1/00).

PERFORMANCE DATA:

See Pharmacia & Upjohn drug insert on Susceptibility Tests - Diffusion Techniques for Linezolid.

SUMMARY OF DEVICE SIMILARITIES

The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug, and Cosmetic Act, as amended and applied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

SUMMARY OF DEVICE SIMILARITIES (continued)

Linezolid Susceptibility Test Discs are substantially equivalent to all of the other susceptibility discs that have been manufactured and marketed by Becton, Dickinson and Company for over twenty years.

Linezolid is a synthetic antibacterial agent of a new class of antibiotics, the oxazolidinones. It is similar to other antimicrobics such as Ciprofloxacin. Linezolid 30 µg BBL Sensi-Discs will be used in a manner analogous to discs used for these and other drugs.

Summary of Substantially Equivalent Components

	Linezolid BBL™ Sensi-Disc™	**Other BBL™ Sensi-Disc™ such as Ciprofloxacin BBL™ Sensi-Disc™**
Intended Use	Antimicrobial susceptibility test disc used for agar diffusion testing with Mueller Hinton agar plates (or Mueller Hinton agar with 5% sheep blood plates for *Streptococcus* species) for susceptibility testing of gram-positive bacteria and gram-negative.	Antimicrobial susceptibility test disc used for agar diffusion testing with Mueller Hinton agar plates (or Mueller Hinton agar with 5% sheep blood plates for *Streptococcus* species or Haemophilus Test Medium Agar for *H. influenzae*) for susceptibility testing of a wide range of gram-positive and gram-negative bacteria.
Result	Qualitative - S/I/R Interpretation	Qualitative - S/I/R Interpretation
Sample	Test organism grown in pure culture on blood or chocolate agar plate.	Test organism grown in pure culture on blood or chocolate agar plate.
Procedure	Antimicrobial discs containing 30 µg of Linezolid are placed on the surface of an inoculated plate; after incubation, zones are read and S/I/R categories determined following NCCLS document M2-A7.	Antimicrobial discs containing 5 µg of Ciprofloxacin are placed on the surface of an inoculated plate; after incubation, zones are read and S/I/R categories determined following NCCLS document M2-A7.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP - 5 2000

Mr. Bradford M. Spring
Manager, Regulatory Affairs
Becton, Dickinson, and Company
Becton Dickinson Biosciences
7 Loveton Circle
Sparks, Maryland 21152

Re: K002165
Trade Name: Linezolid, 30µg, BBL™ Sensi-Disc™
Regulatory Class: II
Product Code: JTN
Dated: July 17, 2000
Received: July 18, 2000

Dear Mr. Spring:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known):

Device Name: Linezolid 30 µg, BBL™ Sensi-Disc™

Indications for Use:

Use of Linezolid 30 µg, BBL™ Sensi-Disc™ for *in vitro* agar diffusion susceptibility testing is indicated when there is a need to determine the susceptibility of bacteria to Linezolid. Linezolid has been shown to be active *in vitro* against most strains of microorganisms listed below, as described in the Pharmacia & Upjohn package insert for this antimicrobic.

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Staphylococcus aureus (including methicillin-resistant strains)
Streptococcus agalactiae
Streptococcus pneumoniae (penicillin-susceptible strains only)
Streptococcus pyogenes

Active *In Vitro* Against:

Aerobic and facultative Gram-positive microorganisms
Enterococcus faecalis (including vancomycin-resistant strains)
Enterococcus faecium (vancomycin-susceptible strains)
Staphylococcus epidermidis (including methicillin-resistant strains)
Staphylococcus haemolyticus
Streptococcus pneumoniae (penicillin-resistant strains)
Viridans group streptococci

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubose

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K002165

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____
(Optional Format 1-2-96)